IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC, Plaintiffs, v. ALCON INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., Defendants.	)	Civil Action No. 04-968 (GMS)

ORDER

1. Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan") filed the above-captioned action against Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, "Alcon") on August 24, 2004. Allergan filed this suit for patent infringement pursuant to 35 U.S.C. § 271(e)(2).[1] The complaint alleges that Alcon infringes U.S. Patent No. 6,673,337 (the "'337 patent") and U.S. Patent No. 6,641,834 (the "'834 patent") because it submitted a § 505(b)(2) application, or paper New Drug Application ("Paper NDA"), to the Food and Drug Administration ("FDA"),

[1] Section 271(e)(2) states, in pertinent part:

> [i]t shall be an act of infringement to submit – an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

seeking approval of its proposed generic brimonidine tartrate ophthalmic drug product.[2] (Compl. ¶¶ 14-15, 17.) Allergan requests injunctive relief and attorney's fees. Allergan's complaint also includes a demand for a jury trial. Alcon filed an answer and counterclaims seeking a declaratory judgment of non-infringement and invalidity. Presently before the court is Alcon's request to strike the jury trial demand interposed by Allergan.

2. The Seventh Amendment governs the right to a jury trial in a civil action and provides that "[i]n suits at common law, where the value in controversy shall exceed twenty dollars, the right of a trial by jury shall be preserved. . . ." U.S. Const. amend. VII. The Seventh Amendment right to a jury trial is thus restricted to suits "at common law," and does not apply to suits at equity. *Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 565 (1990). The United States Supreme Court has articulated a two-part Seventh Amendment inquiry:

> To determine whether a particular action will resolve legal rights, we examine both the nature of the issues involved and the remedy sought. "First, we compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity. Second, we examine the remedy sought and determine whether it is legal or equitable in nature." *Tull v. United States*, 481 U.S. 412, 417-418 (1987). The second inquiry is the more important in our analysis. *Granfinanciera, S.A. v. Nordberg*, 429 U.S. 33, 42 (1989).

Chauffeurs, 494 U.S. at 565.

3. According to the Federal Circuit, the "nature of the underlying controversy," is the important question to consider when determining whether a party is entitled to a jury trial. *In re*

[2] Alcon also filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4), or Paragraph IV Certification, alleging that the '337 and '834 patents are invalid and/or not infringed by its product.

Lockwood, 50 F.3d 966, 973 (Fed. Cir.), *vacated*, 515 U.S. 1182 (1995).[3] Alcon contends that there is no Seventh Amendment right to a jury trial in section 271(e)(2) actions because the nature of the action and the remedies available are equitable. Alcon also contends that its declaratory judgment counterclaims do not create a right to a jury trial. Allergan, on the other hand, asserts that it is entitled to a jury trial on Alcon's declaratory judgment counterclaims for invalidity and non-infringement.

4. After having considered the parties submissions on the issue (D.I. 63, 66, 80), the court concludes that the nature of the underlying controversy in this case is equitable. The Supreme Court has emphasized that the act of filing a 505(b)(2) application creates a "highly artificial act of infringement" for purposes of 35 U.S.C. § 271(e)(2). *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Because patent infringement under section 271(e)(2) is "artificial," the remedies available under 35 U.S.C. § 271(e)(4) are limited. "[D]amages or other monetary relief may be awarded against an infringer *only* if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product." 35 U.S.C. § 271(e)(4)(C) (emphasis added).[4] Here, Allergan has not alleged

---

[3] The *Lockwood* decision was vacated by the Supreme Court. However, the Federal Circuit has stated that "[t]he Supreme Court vacated *Lockwood* without explanation. Thus, our analysis has been neither supplanted nor questioned. Although no longer binding we find its reasoning pertinent." *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1339 (Fed. Cir. 2001).

[4] The full text of section 271(e)(4) states:

> (4) For an act of infringement described in paragraph (2)--
>
> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

that Alcon commercially manufactures, uses, offers for sale, or sells its generic brimonidine tartrate ophthalmic drug product. Thus, Allergan is entitled only to injunctive relief.[5] As such, "the nature of the underlying controversy is entirely equitable, involving only a controversy whether future acts should be enjoined," and there is no right to a jury trial in this case. *In re Apotex, Inc.*, 49 Fed. Appx. 902, 903 (Fed. Cir. 2002) (not precedential)[6]; *see Lockwood*, 50 F.3d at 976 (In 18th Century England, "if the patentee . . . sought *only* to enjoin future acts of infringement, the patentee could only bring a suit in equity, and the defense of invalidity ordinarily would be tried to the bench."); *Shubin v. United States Dist. Court*, 313 F.2d 250 (9th Cir. 1963), *cert. denied*, 373 U.S. 936 (1963) (no jury trial because the patentee sought only injunctive relief in its counterclaim of infringement).

> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
>
> (C) damages or other monetary relief may be awarded against an infringer *only* if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.
>
> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4)

[5] Allergan agrees that it is only entitled to injunctive relief. Its letter (D.I. 66) to the court in support of its jury demand states "Section 271(e)(4) specifies that the patentee may only sue for injunctive relief prior to the generic product being approved and sold, as Allergan has done here." (D.I. 66, at 2.)

[6] Although the Federal Circuit's holding in *In re Apotex, Inc.*, 49 Fed. Appx. 902, 903 (Fed. Cir. 2002) is non-precedential and cannot be cited as binding, the court finds its reasoning persuasive.

Therefore, IT IS HEREBY ORDERED that:

1. Alcon's request to strike the jury trial demand interposed by Allergan (D.I. 63) is GRANTED.

2. The jury demand in Civil Action No. 04-968 (GMS) is hereby stricken.

.

Dated: July 22 , 2005

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE